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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/900,627	07/06/2001	Charles David Weaver	3035-4086US1	7563	
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LOUIS J. WILLE			CHEU, CHANGHWA J		
BRISTOL-MYERS SQUIBB COMPANY			ART UNIT	PAPER NUMBER	
PATENT DEP	ARTMENT		AKTONII	TALER NOMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)	
		09/900,627	WEAVER ET AL.	
	Office Action Summary	Examiner	Art Unit	
		Jacob Cheu	1641	
Pariod fo	The MAILING DATE of this communication	appears on the cover sheet wi	h the correspondence address	
WHI(- Exte after - If NO - Failt Any	IORTENED STATUTORY PERIOD FOR RECHEVER IS LONGER, FROM THE MAILING insions of time may be available under the provisions of 37 CFR SIX (6) MONTHS from the mailing date of this communication. O period for reply is specified above, the maximum statutory per ure to reply within the set or extended period for reply will, by state to reply within the set or extended period for reply will, by state to reply within the set or extended period for reply will, by state to the provided by the Office later than three months after the material part of the provided patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNIC R 1.136(a). In no event, however, may a re- tiod will apply and will expire SIX (6) MON atute, cause the application to become AB	CATION. ply be timely filed ITHS from the mailing date of this communication ANDONED (35 U.S.C. § 133).	
Status				
1)⊠ 2a)□ 3)□	Responsive to communication(s) filed on <u>00</u> . This action is FINAL . 2b) To Since this application is in condition for allow closed in accordance with the practice under	his action is non-final. wance except for formal matte		is
Disposit	ion of Claims			
5)□ 6)⊠ 7)⊠ 8)□ Applicat	Claim(s) 1-120 is/are pending in the applica 4a) Of the above claim(s) 32-120 is/are with Claim(s) is/are allowed. Claim(s) 1-5 and 8-31 is/are rejected. Claim(s) 6-7 is/are objected to. Claim(s) are subject to restriction and ion Papers The specification is objected to by the Exam	drawn from consideration. d/or election requirement.		
10)	The drawing(s) filed on is/are: a) a Applicant may not request that any objection to the Replacement drawing sheet(s) including the contract the oath or declaration is objected to by the	accepted or b) objected to lead on the drawing(s) be held in abeyan rection is required if the drawing(ce. See 37 CFR 1.85(a). s) is objected to. See 37 CFR 1.121((d).
Priority (under 35 U.S.C. § 119			
а)	Acknowledgment is made of a claim for fore All b) Some * c) None of: 1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the p application from the International Bun See the attached detailed Office action for a l	ents have been received. ents have been received in Apriority documents have been eau (PCT Rule 17.2(a)).	oplication No received in this National Stage	
Attachmen	t(s)			
1)	te of References Cited (PTO-892) te of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/ tr No(s)/Mail Date	Paper No(s	ummary (PTO-413) I/Mail Date formal Patent Application (PTO-152) 	

Art Unit: 1641

DETAILED ACTION

Applicant's amendment filed on 5/6/2005 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

Claims 1-31 are under examination. Claims 32-120 are withdrawn from further consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, line 9, it is not clear about this term "sealant" and its relations to the apparatus.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. Claims 1, 2, 12-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Meyer et al. (WO 99/19729, note the English equivalent is US 6379916).

Art Unit: 1641

Meyer et al. teach an apparatus for measuring cellular electrical condition wherein the apparatus comprises a first layer having a non-conductive material comprising a top surface and bottom surface and including one or more pores each extending between, and through, said top and bottom surface wherein the top surface of the material comprises one or more cell attachment sites circumscribing the pores, wherein the pores of the materials are capable of forming electrical tight seals with contacted cells at the attachment sites, and a second layer comprising a non-conductive, sealant material which directly contacts the first layer of the cell support membrane and spans across at least one pore (Col. 3, line 52-67; Figure 3, See component 2-4).

With respect to claim 2, the apparatus taught by Meyer et al. is for measuring cellular electrical potential (Col. 1, line 25-45).

With respect to claim 12-13, the apparatus taught by Meyer et al. comprising multiple of pores on the surface (See Figure 1-3).

With respect to claims 15-16, the apparatus taught by Meyer et al. can be used to ion potential change in the neuron cells (Col. 1 to Col.2).

With respect to claims 17-19, the cellular potential is coupled with G-protein, or ion transporter protein (Col. 1 to Col. 2).

With respect to claims 20-27, the features "the area of the second layer of the cell support membrane component is <u>removable</u>" from the instant invention is inherently obtainable by the recited device. The case law has established that the production of a product by a particular process does not impart novelty or unobviousnes to a product when the same product is taught by the prior art-"[Where] the claimed and prior art products are identical or substantially identical in *structure or composition*, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness

Application/Control Number: 09/900,627 Page 4

Art Unit: 1641

has been established." In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)(emphasis added). This is particularly true when the properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Therefore, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product per se, even when limited to the particular process, is unpatentable over the same product taught by the prior art. See In re Kind, 207 F.2d 618, 620, 43 USPQ 400, 402 (CCPA 1939); In re Merz, 97 F.2d 599, 601, 38 USPQ 143, 144-145 (CCPA 1938); In re Bergy, 563 F.2d 1031, 1035, 195 USPQ 344, 348 (CCPA 1977) vacated 438 U.S. 902 (1978); and United States v. Ciba-Geigy Corp., 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979). The second layer of the Meyer's apparatus, i.e. a filter, can be removed by photo-ablation assisted by confocal microscope. Note, Figure 1 of Meyer et al. reference is an embodiment without the second layer (See Figure 1).

With respect to claims 28-29, Meyer et al. teach a chamber to hold the cell support apparatus in an electrolyte solution (See Figure 4).

With respect to claim 30-31, Meyer et al. teach using "patch-clamp" technique to measure the cellular potential in the sample. It is inherent that two electrodes, e.g. ground and measuring electrodes are used in the system to measure the difference electrical potential of the cells (Col. 1, line 1-65).

Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Application/Control Number: 09/900,627 Page 5

Art Unit: 1641

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer et al. in view of Farb et al. (US 5366968).

Meyer et al. reference has been discussed but is silent disclosing what materials used for the cellular support on the first layer.

Farb et al. teach device for measuring cellular electrophysiological potential. Farb et al. teach that the cellular support materials can be of glass pipette (Col. 3, line 35-45).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Meyer et al. with the glass pipette as taught by Farb et al since both references are in analogous field and use varying materials for cellular support involves merely routine skill in the art.

6. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer et al. in view of Shimizu et al. (US 4600507).

Art Unit: 1641

Meyer et al. reference has been discussed but does not explicitly disclosing what materials are used for the second filter layer.

Shimizu et al. disclose several suitable materials for cellular filter, including cellulose, polyethylene terephthalate (Col. 6, line 30-40).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Meyer et al. with the materials of cellulose filter as taught by Shimizu et al. because it is well-known using different materials for cellular filter, such as cellulose, and such technique involves routine practice in the art.

7. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer et al. in view of Baumann et al. (US 6475760).

Meyer et al. reference has been discussed but is silent in teaching treating support membrane with poly-L-lysine for facilitation of cell attachment.

Baumann et al. teach using fibronectin, poly-L-lysine for facilitation of cell attachment for measuring cellular electrophysiological potential (Col. 3, line 30-32; Col. 6, line 27-37).

8. Claim 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer et al. in view of Bossuyt et al. (US 6585969).

Meyer et al. reference has been discussed but does not explicitly teach using materials, such as silicone or Teflon, to inhibit cell attachment.

Bossuyt et al. teach treating the cell culture vessel with silicone will make the walls sufficiently hydrophobic to prevent cell adhesion to increase specificity for cell culturing (Col. 14, last paragraph to Col. 15, line 1-2).

Art Unit: 1641

Therefore, it would have been obvious to have motivated one skilled in the art at the time when invention was made to have provided Meyer et al. to apply the treatment of silicone to the outside of the cell attachment site as taught by Bossuyt et al. to further increase cell attachment to the target area because silicone treatment to the outside of the cell attachment site can prevent cell from adhesion outside of the electrical measurement area and cause more specific and efficient cell attachment to the electrical measurement area.

Response to Applicant's Arguments

9. Applicant's arguments with respect to claims 1-31 have been considered but are moot in view of the new ground(s) of rejection.

The enablement rejections of claims 1-31 under 35 USC, 112, first paragraph, are withdrawn.

Meyer et al. reference

Applicant pointed out the reference of Meyer et al. (under enablement rejection set forth in the previous Office Action) (emphasis added), that the second layer of Meyer et al. is a filter (component 4 in Figure 3) which provides passage to allow fluids to pass through the first layer. Applicant pointed out that there is no disclosure or suggestion in Meyer et al. teaching use of a sealant layer as set forth in the recited features.

As set forth in this Office Action, particularly the term "sealant" is not clear with respect to the relation to the apparatus (See Rejections under 35 USC 112, second paragraph). It is not clear what materials, or component this layer applicant intends to "seal". As pointed out by applicant, "[t]he filter 4 is provided to allow passage of the rinsing fluid, yet to prevent blockage of the pores in the substrate 1 by small particles" (See Remarks, page 19, second paragraph).

Art Unit: 1641

Examiner considers that the filter used by Meyer et al. also serves as a sealant layer as admitted by the applicant to prevent small particles to pass. Also, this second layer is also sealant to prevent the target cell to pass through the pores (See Figure 3). Furthermore, one of the materials used to make the second layer is cellulose which is also a common materials used for making filter in the art (See claim 5).

Allowable Subject Matter

- 10. Claims 6-7 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
- The following is a statement of reasons for the indication of allowable subject matter: no prior art teaches or suggests an apparatus for measuring cellular electrical conditions comprising a second layer wherein a Solvent Blue 14 dye is contained for subsequent facilitation of photoablation. The nearest prior art is the teachings of Meyer et al. where Meyer et al. teach using a second layer, e.g. filter, as the sealant layer but Meyer et al. do not disclose or suggest this filter containing a dye for subsequent photo-ablation removal.

Conclusion

12. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu Examiner Art Unit 1641

October 26, 2005

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Page 9